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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	9

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/500,135	ESTELL ET AL.	
	Examiner	Art Unit	
	David A Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

18)☐ Interview Summary (PTO-413) Paper No(s). _____ .

19)☐ Notice of Informal Patent Application (PTO-152)

20)☒ Other: RANDOM SEQUENCE LISTING ERROR REPORT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4-10 and 14-15, drawn to variant polypeptides producing a lessened immunogenic response, classified in class 424, subclass 184.1+, class 435, subclass 183+, or class 530, subclass 350+, for example.

II. Claims 1, 3-10 and 14-15, drawn to variant polypeptides producing a greater immunogenic response, classified in class 424, subclass 184.1+, class 435, subclass 183+, or class 530, subclass 350+, for example.

III. Claims 11-13, drawn to nucleic acids, vectors and cells, encoding polypeptides producing a lessened immunogenic response, classified in class 435, subclass 320.1 and 325+ and class 536, subclass 23.1+.

IV. Claims 11-13, drawn to nucleic acids. Vectors and cells encoding polypeptides producing a greater immunogenic response, classified in class 435, subclass 320.1 and 325+ and class 536, subclass 23.1+.

V. Claims 16-18, drawn to enzyme compositions comprising naturally occurring enzymes, classified in class 435, subclass 183+.

VI. Claims 19-23, drawn to methods of determining an immunogenic response produced by a protein, classified in class 435, subclass 6, 7.24, and 377.

VII. Claims 24-28, drawn to methods of altering the immunogenicity of a polypeptide, classified in class 435, subclass 7.24.

Note that claims 1, 4-10, and 14-15 will be examined for only the elected embodiment of Group I or Group II. Applicant is further requested to identify any claims dependent from claim 1 that do not belong to the elected Group, by virtue of their limitations. Note that claims 11-13 will be examined for only the elected embodiment of Group III or Group IV.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to variant polypeptides having different modes of operation (in Group I the polypeptides produce a lessened immunogenic response, while in Group II the polypeptides produce a greater immunogenic response) and would not be capable of use together. A reference showing one (e.g. a vaccine with a T-cell epitope altered to heighten an immune response to a vaccine) would not show or suggest the other (e.g. a cleaning composition a T-cell epitope of an enzyme altered to lessen an immune response). For a like reason, Groups IIII and IV are unrelated

Inventions I/II and III/IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, that is the polypeptides of Groups I/II and the

nucleic acids of Groups III/IV, are different compositions with different properties and functions. Further polypeptides with altered T-cell epitopes can be obtained without encoding such with a nucleic acid; for example, the T-cell epitopes can be altered by derivatization with PEG.

Inventions I/II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions would not be used together, since one would either obtain an enzyme with an altered T-cell epitope or else obtain a naturally occurring enzyme which requires no further alteration for use in the composition.

Inventions I/II/V and VI are related as product and process of use (product evaluation). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I/II/V can be evaluated for their immunogenicities by alternate methods. For example in vivo skin tests can be used, or alternative types of in vitro tests can be used that do not involve differentiated dendritic cells.

Inventions VII and I/II/V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant's attention is drawn to the attached Raw Sequence Listing Error Report.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Fri., 8:15 am-4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3704 for responses to restriction requirement communications; use attached form.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644

RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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COMMENTS: _____

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IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

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